K112605

MAY - 4 2012

510(k) SUMMARY

J. MORITA USA Inc.'s
Tri Auto mini

1. NAME OF DEVICE

Common/Usual Name: Endodontic Treatment Motorized Handpiece
Device trade or proprietary name: Tri Auto mini
Product Model : TR-CM

2. SUBMITTER NAME AND ADDRESS WITH PHONE/FAX

Registration No. 2081055	Registration No. 3002807636
Initial Distributor:	Manufacturer:
J. Morita USA, Inc.	J. MORITA MFG. CORP.
9 Mason	680 Higashihama Minami-cho
Irvine, CA 92618	Fushimi-ku, Kyoto
USA	Japan 612-8533
Telephone: 949-581-9600	+81-75-611-2141
Facsimile: 949-581-9688	+81-75-605-2354

3. CONTACT PERSON

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

4. DATE SUMMARY PREPARED: August 5, 2011

5. DEVICE CLASSIFICATION/CLASSIFICATION PANEL

Device: Endodontic Treatment Motorized Handpiece
Review Panel: 872 Dental
Product Code: EKX
Device Class: Class I

6. DEVICE DESCRIPTION/SUBSTANTIAL EQUIVALENCE

DEVICE DESCRIPTION

The Tri Auto mini is an battery-driven handpiece with a motor, equipped with the chuck for holding rotary instrument such as a dental file and a reamer. Tri Auto mini can be used for enlargement and preparation of root canals. When connected to Apex Locator (which is not included in this application), the Tri Auto mini indicates the position of the file tip inside the root canal.

SUBSTANTIAL EQUIVALENCE

The Tri Auto mini is substantially equivalent to Tri Auto ZX (K921979 / K953867) and ROOT ZX II (K071190).

1) **Predicate device I : Tri Auto ZX (K921979 / K953867)**

The Tri Auto mini is substantially equivalent to Tri Auto ZX from J.MORITA MFG.CORP. The Tri Auto mini has similar general intended uses, similar principles of operation, and similar technological characteristics to the predicate device Tri Auto ZX (K970339).

2) **Predicate device II : ROOT ZX II (K071190)**

The Tri Auto mini is substantially equivalent to ROOT ZX II (K071190) from J.MORITA MFG.CORP. The Tri Auto mini has similar general intended uses, similar principles of operation, and similar technological characteristics to the predicate device, ROOT ZX II (K071190).

PERFORMANCE TESTING

The Tri Auto mini was tested in accordance with IEC 60601-1, IEC 60601-1-4, UL 60601-1, CAN/CSA C 22.2 No.601.1-M90, and IEC 60601-1-2. Also, Biocompatibility, sterilization, and software validation were conducted.

Test results shows that Tri Auto mini is substantially equivalent to predicate devices.

Table- 1 Comparison summary table

	Predicate devices	
TECHNOLOGICAL CHARACTERISTICS of Tri Auto mini	**Tri Auto ZX (K970339)**	**ROOT ZX II (K071190)**
Indication for use Canal Enlargement Function	**Identical**	**Identical**
Target population	**Identical**	**Identical**
Design	**Similar**	**Different**
Materials	**Similar**	**Similar**
Performance Canal Enlargement Function	**Identical**	**Identical**
Sterility	**Similar**	**Similar**
Biocompatibility	**Similar**	**Similar**
Mechanical safety	**Identical**	**Identical**
Chemical safety	**Identical**	**Identical**
Anatomical sites	**Similar**	**Similar**
Human factors	**Similar**	**Similar**
Energy used and/or delivered	**Different**	**Different**
Compatibility with environment and other devices	**Similar**	**Similar**
Where used	**Identical**	**Identical**
Standards met	**Similar**	**Identical**
Electrical safety	**Similar**	**Identical**
Thermal safety	**Identical**	**Identical**

7. INDICATIONS FOR USE

The Tri Auto mini motorized handpiece can be used to enlarge and prepare root canals, remove gutta-percha points, and for professional tooth cleaning. When connected to Apex locator, the Tri Auto mini can be used to measure the length of root canals.

8. Conclusion

Based on the information provided in this premarket notification, the Tri Auto mini is substantially equivalent to the Tri Auto ZX (K970339) and the ROOT ZX II (K071190).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

J. Morita USA, Inc.
C/O Mr. Keith A. Barritt
Attorney
Fish & Richardson P.C.
1425 K Street NW
Suite 1100
Washington, District of Columbia 20005

MAY - 4 2012

Re: K112665
Trade/Device Name: Tri Auto Mini (Endodontic Treatment Motorized Handpiece)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories.
Regulatory Class: I
Product Code: EKX
Dated: April 30, 2012
Received: May 1, 2012

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): unknown

Device Name: Tri Auto mini (Endodontic Treatment Motorized Handpiece)

Indications For Use:

The Tri Auto mini motorized handpiece can be used to enlarge and prepare root canals, remove gutta-percha points, and for professional tooth cleaning.
When connected to Apex locator, the Tri Auto mini can be used to measure the length of root canals.

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112665

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)